REMARKS

The Office Action of December 14, 2006, has been received and reviewed.

Claims 6-49 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

Supplemental Information Disclosure Statement

Please note that a Supplemental Information Disclosure Statement was filed in the above-referenced application on March 29, 2006, but that the undersigned attorney has not yet received any indication that the references cited in the Supplemental Information Disclosure Statement have been considered in the above-referenced application. It is respectfully requested that the references cited in the Supplemental Information Disclosure Statement of March 29, 2006, be considered and made of record in the above-referenced application and that an initialed copy of the Form PTO/SB/08A that accompanied that Supplemental Information Disclosure Statement be returned to the undersigned attorney as evidence of such consideration.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 6-49 are rejected under 35 U.S.C. § 112, first paragraph, for reciting subject matter that purportedly lacks an adequate written description in the as-filed specification of the above-referenced application.

Claims 6, 14-16, 20-22, 25, 26, 29, 31-35, 42, 43, and 46 have been rejected because the as-filed specification purportedly lacks an adequate written description of a "probability of effectiveness" ("probability of desired effectiveness" in claim 35) of at least one drug. It is respectfully submitted that the as-filed specification does, in fact, provide nonlimiting examples of "a probability of effectiveness" at several locations. *See, e.g.,* FIGURES 23, 24, 36; page 6, lines 20-22; page 43, line 20, to page 44, line 11; page 50, line 19, to page 51, line 4. As a specific example, the as-filed specification, at page 44, lines 1-4, explains that "[p]ast, current and predicted concentrations are normalized with respect to the drug's EC95 value (the drug

concentration at which 95% of the population is completely affected by the anesthetic drug) and plotted relative to the time... that it was administered."

In the 35 U.S.C. § 112, first paragraph, rejections of claims 7, 14, and 31, it was asserted that the recitation "causing the subject to lose consciousness; eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain; or causing a measurable level of muscle relaxation" constitutes new matter. It is respectfully submitted that this recitation is not new matter, as the as-filed specification, at page 44, lines 9-11, and in FIGURES 23 and 24 provides a written description regarding the probability that a drug or combination of drugs has a desired sedative effect, a desired analgesic effect, and a desired muscle relaxant effect, which one of ordinary skill in the art would readily understand as corresponding to the elements recited in claims 7, 14, and 31.

Claim 18 stands rejected for reciting that "there is a ninety-five percent probability" that a concentration of at least one drug has a desired effect, which recitation assertedly constitutes new matter. Again, the as-filed specification, at page 44, lines 1-4, and in FIGURES 23 and 24 provides a written description regarding concentrations at which there is a 95% chance that a drug will have the desired effect on a subject.

Claims 7-13, 17, 19, 23, 24, 27, 28, 30, 36-41, 44, 45, and 47-49 were rejected for depending from rejected base claims.

In view of the foregoing, it is respectfully submitted that each of claims 6-49 complies with the written description requirement of the first paragraph of 35 U.S.C. § 112. Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of each of these claims is respectfully solicited, as is their allowance.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 35 is rejected under 35 U.S.C. § 112, second paragraph, for being drawn to subject matter that is allegedly indefinite.

Claim 35 has been rejected for reciting a "system for modeling" in the preamble, and a system for modeling and displaying in the body. The preamble of claim 35 has been revised for consistency with the preamble. Accordingly, it is respectfully submitted that any indefiniteness has been removed without altering the scope of claim 35.

Withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claim 35 is respectfully requested, as is the allowance of claim 35.

Obviousness-Type Double Patenting Rejection

Claims 6-12 and 14 have been rejected under the judicially created doctrine of obviousness-type double patenting for reciting subject matter that is assertedly unpatentable over the subject matter to which claims 6-11, 15, and 19 of U.S. Application Ser. No. 10/269,422 are directed, in view of the teachings of U.S. Patent 5,522,798 to Johnson (hereinafter "Johnson").

It is respectfully requested that the obviousness-type double patenting rejection be held in abeyance until all other issues have been resolved in the above-referenced application.

Rejections under 35 U.S.C. § 103(a)

Claims 6-15 and 20-49 have been rejected under 35 U.S.C. § 103(a)

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Howson in View of Johnson

Claims 6, 8-10, 12, 13, 15, 20, 21, and 41-43 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the subject matter taught in U.S. Patent 5,088,981 to Howson (hereinafter "Howson"), in view of teachings from Johnson.

Independent claim 6 is directed to a system for data representation. Among other things, the system of independent claim 6 includes a drug display monitor. The drug display monitor of

independent claim 6 is configured to depict, in real time, a present "probability of effectiveness" of at least one drug introduced into the subject by the drug delivery system and future "probabilities of effectiveness" of the one or more drugs in the subject.

The teachings of Howson relate to portable drug delivery devices that may be programmed to deliver drugs in accordance with "pharmacokinetic, pharmacodynamic, or dose-response models . . . to either aid programming of the delivery profile . . . or to simulate the outcome of a profile in terms of resulting bodily concentrations . . ." Col. 7, lines 37-43. Specifically, a computer is used to program a drug dose profile into a logic chip. The logic chip is then removed from the computer and assembled with a portable drug delivery unit.

Johnson also teaches portable drug delivery devices. The portable drug delivery devices of Johnson may be programmed to deliver drugs in accordance with a model that controls a blood plasma drug concentration or an effect compartment drug concentration (*i.e.,* the concentration of a drug at a particular location in a patient's body – *see, e.g.,* col. 9, line 47, to col. 14, line 64) in a desired manner. Col. 3, lines 26-34.

It is respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 6, 8-10, 12, 13, 15, 20, 21, and 41-43 since neither Howson nor Johnson, taken either alone or together, teaches or suggests each and every element of any of these claims.

In particular, with respect to the subject matter recited in independent claim 6, Howson and Johnson both lack any teaching or suggestion of a drug display monitor that is configured to depict, graphically and substantially in real time, a probability of effectiveness of at least one drug. Although Howson teaches that the computer may simulate drug delivery by the drug delivery unit before the drug dose profile is written to the logic chip and supplied to the drug delivery device, Howson provides no teaching or suggestion that the computer or the drug delivery device may display, in real time, a present "probability of effectiveness" of at least one drug. Johnson teaches a display by which "instructions and data are presented to a user" (col. 5, line 66, to col. 6, line 2), but lacks any teaching or suggestion that relates to a "probability of effectiveness" of at least one drug.

Each of claims 8-10, 12, 13, 15, 20, 21, and 41-43 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 6, which is allowable.

Claim 12 is additionally allowable because neither Howson nor Johnson includes any teaching or suggestion of a system that includes a normalizer. Rather, the teachings of Howson and Johnson are limited to system that are configured to model and, optionally, display raw (*i.e.*, non-normalized) drug concentration data.

Claim 43 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

It is further submitted that, in view of the fact that neither Howson nor Johnson teaches or suggests each and every element of any of claims 6, 8-10, 12, 13, 15, 20, 21, and 41-43, without the benefit of hindsight that has been provided to the Office by the claims of the above-referenced application, one of ordinary skill in the art wouldn't have been motivated to combine teachings from Howson and Johnson in the asserted manner or had any reason to expect that the asserted combination of reference teachings would have been successful.

Therefore, a *prima facie* case of obviousness has not been set forth against any of claims 6, 8-10, 12, 13, 15, 20, 21, and 41-43. Accordingly, it is respectfully submitted that each of these claims is directed to subject matter that, under 35 U.S.C. §103(a), is allowable over the teachings of Howson and Johnson.

Howson in View of Teeple

Claims 7 and 11 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is assertedly unpatentable over teachings from Howson, in view of the subject matter taught in U.S. Patent 5,925,014 to Teeple Jr. (hereinafter "Teeple").

Claims 7 and 11 are both allowable, among other reasons, for depending directly or indirectly from amended independent claim 6, which is allowable.

Howson, Johnson, and Teeple

Claims 14, 22-40, and 44-49 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over that taught in U.S. Patent 5,088,981 to Howson (hereinafter "Howson"), in view of teachings from U.S. Patent 5,522,798 to Johnson and further in view of teachings from U.S. Patent 5,925,014 to Teeple.

Independent claim 14 recites a system for data representation that includes, among other things, a display monitor that is configured to depict, graphically and substantially in real-time, a modeled "probability of effectiveness" of at least one drug in a subject. The "probability of effectiveness" includes a probability that the at least one drug will cause the subject to lose consciousness, a probability of eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain experienced by the subject, and a probability of causing a measurable level of muscle relaxation in the subject.

Independent claim 35 is drawn to a system for modeling a probability of desired effectiveness of at least one drug in a subject. The system of independent claim 35 includes a processing element and an output element. The processing element is programmed to model a concentration of at least one drug in a subject over time. The output element is configured to display, substantially in real-time, a modeled concentration of the at least one drug "in reference to at least one concentration at which the at least one drug will have a desired effect" on a known percentage of a population.

Teachings from Howson and Johnson have been summarized above.

The teachings of Teeple are drawn to systems in which one of more drugs may be pre-mixed and pre-dosed for administration at a standardized dose (*i.e.,* predetermined) rate.

It is respectfully submitted that there are several reasons that teachings from Howson, Johnson, and Teeple, taken either separately or in combination, do not support a *prima facie* case of obviousness against any of claims 14, 22-40, or 44-49.

First, it is respectfully submitted that Howson, Johnson, and Teeple do not teach or suggest each and every element of any of claims 14, 22-40, or 44-49.

With respect to independent claim 14, each of Howson, Johnson, and Teeple lacks any teaching or suggestion of a drug display monitor that is configured to depict, graphically and

substantially in real time, a probability of effectiveness of at least one drug. Further, it is respectfully submitted that none of Howson, Johnson, or Teeple teaches or suggests a system with a drug display monitor that is configured to depict a probability of effectiveness of at least one drug at causing a subject to lose consciousness, at eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain, or at causing a measurable level of muscle relaxation in the subject.

Howson merely mentions that the computer, or "programming unit 13," disclosed therein includes "one or more displays **28**" (col. 6, lines 37-44), while Johnson's teachings are limited to a display by which "instructions and data are presented to a user" (col. 5, line 66, to col. 6, line 2), and the Teeple merely shows a mix controller 48 (laptop computer) that includes a display (FIGs. 2 and 3).

As such, under 35 U.S.C. § 103(a), the subject matter recited in independent claim 14 is allowable over the subject matter disclosed in Howson, Johnson, and Teeple.

Each of claims 22-34, and 44-46 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 14, which is allowable.

Claim 27 is also allowable since neither Howson nor Johnson teaches or suggests a system that includes a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood that the at least one drug has a desired effect. Again, the teachings of Howson and Johnson are limited to devices that depict raw drug concentrations rather than the probability that the manner in which a particular drug is administered will have a certain effect on a subject.

Claim 28, which depends from claim 27, is additionally allowable because Howson and Johnson include no teaching or suggestion of a system with a drug display monitor that depicts a probability of effectiveness of a drug as a percent likelihood based on results from a predefined population.

Claims 29 and 30 are further allowable since the system of each of Howson and Johnson lacks a display monitor that depicts an element representing a concentration at which there is a ninety-five percent probability the at least one drug will have a desired effect.

Claim 31 is additionally allowable since none of Howson, Johnson, or Teeple teaches or suggests a system with a process that is configured to model a probability of effectiveness of at least two anesthetic agents at causing the subject to lose consciousness, at eliminating or blocking

laryngoscopy pain, incision pain, or intraoperative pain, or at causing a measurable level of muscle relaxation in the subject.

Claim 46 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

As for the system of independent claim 35, it is respectfully submitted that Howson, Johnson, and Teeple each lack any teaching or suggestion of a system that displays a modeled concentration of at least one drug "in reference to at least one concentration at which the at least one drug will have a desired effect" on a known percentage of a population. The teachings of Howson are limited to methods and systems for developing, simulating, and effecting drug delivery protocols, without any teaching or suggestion that that a modeled likelihood that one or more drugs will have desired effects on a subject may be displayed. The teachings of Johnson relate to administration of drugs to achieve specific effect compartment *concentrations* (*i.e.*, P_k), without teaching or suggesting that the likelihood that the drugs will have desired effects on a subject may be modeled or displayed. Teeple teaches a system in which drugs are mixed for administration in a predetermined, standardized rate profile, but does not teach or suggest that the disclosed system may model or display the likelihood that the drugs will have desired effects on a subject.

Claims 36-40 and 47-49 are each allowable, among other reasons, for depending directly or indirectly from amended independent claim 35, which is allowable.

Claim 37 is also allowable because none of Howson, Johnson, or Teeple teaches or suggests a system with a processing element that is configured to model a desired effect in terms of the abilities of at least two anesthetic agents to cause a subject to lose consciousness, to eliminate or block laryngoscopy pain, incision pain, or intraoperative pain, or to cause a measurable level of muscle relaxation in the subject.

Claim 49 is further allowable since Howson and Johnson both lack any teaching or suggestion of a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

Additionally, it is respectfully submitted that, without the benefit of hindsight provided by the claims of the above-referenced application, one of ordinary skill in the art wouldn't have been motivated to combine teachings from Teeple with the teachings of Howson or Johnson. That is because the teachings of Teeple relate to a technique whereby drugs are mixed so as to fit into a standardized delivery, or dosage, scheme or protocol, whereas Howson and Johnson teach methods, apparatus, and system that are configured deliver drugs in a manner that is tailored to a particular subject.

It is, therefore, respectfully submitted that the teachings of Howson, Johnson, and Teeple do not support a *prima facie* case of obviousness against any of claims 14, 22-40, and 44-49, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

Withdrawal of the 35 U.S.C. §103(a) rejections of claims 6-15 and 20-49 is respectfully requested, as is the allowance of each of these claims.

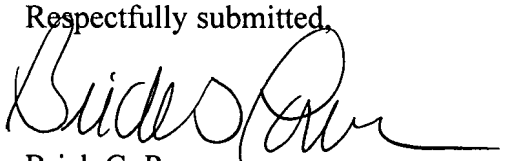
Allowable Subject Matter

No prior art rejections were asserted against any of claims 16-19. As the only rejection presented against these claims was a 35 U.S.C. § 112, first paragraph, written description rejection, and since an adequate written description of the subject matter recited in each of these claims has been provided in the as-filed specification, it is respectfully submitted that the subject matter recited in each of claims 16-19 is allowable.

CONCLUSION

It is respectfully submitted that each of claims 6-49 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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